

BETH C. DRAIN, CA CSR NO. 7152

BEFORE THE  
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE  
AND THE APPLICATION REVIEW SUBCOMMITTEE  
TO THE  
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE  
ORGANIZED PURSUANT TO THE  
CALIFORNIA STEM CELL RESEARCH AND CURES ACT  
REGULAR MEETING

LOCATION: AS INDICATED ON THE AGENDA

DATE: THURSDAY, JANUARY 18, 2018  
11 A.M.

REPORTER: BETH C. DRAIN, CSR  
CA CSR. NO. 7152

FILE NO.: 2018-01

I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION	
1. CALL TO ORDER.	3
2. ROLL CALL.	3
3. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE PROJECTS	4
CLOSED SESSION	NONE
4. DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE PROJECTS (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
5. PUBLIC COMMENT.	NONE
6. ADJOURNMENT.	9

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THURSDAY, JANUARY 18, 2018; 11 A.M.

CHAIRMAN THOMAS: OKAY. GIVEN THAT, I'D  
LIKE TO CALL THE REGULAR MEETING OF THE ICOC AND THE  
APPLICATION REVIEW SUBCOMMITTEE FOR JANUARY 2018 TO  
ORDER. MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: HERE.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: SHERRY LANSING.

MS. LANSING: HERE.

MS. BONNEVILLE: DAVE MARTIN.

DR. MARTIN: HERE.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: HERE.

MS. BONNEVILLE: ADRIANA PADILLA.

DR. PADILLA: HERE.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: HERE.

MS. BONNEVILLE: ROBERT QUINT.

DR. QUINT: HERE.

MS. BONNEVILLE: JEFF SHEEHY.

SUPERVISOR SHEEHY: HERE.

MS. BONNEVILLE: JONATHAN THOMAS.

1 CHAIRMAN THOMAS: HERE.

2 MS. BONNEVILLE: DIANE WINOKUR.

3 MS. WINOKUR: HERE.

4 MS. BONNEVILLE: ARE THERE ANY OTHER BOARD  
5 MEMBERS ON THE LINE? THANK YOU.

6 CHAIRMAN THOMAS: THANK YOU, MARIA.

7 WE'LL GO STRAIGHT TO ITEM 3, CONSIDERATION  
8 OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL  
9 TRIAL STAGE PRODUCTS. WE'LL TURN THE MEETING OVER  
10 TO SUPERVISOR SHEEHY.

11 SUPERVISOR SHEEHY: THANK YOU, J.T.

12 SO, DR. SAMBRANO, DO YOU HAVE A  
13 PRESENTATION FOR US TODAY?

14 DR. SAMBRANO: YES. THANK YOU, SUPERVISOR  
15 SHEEHY.

16 MEMBERS OF THE BOARD, SO YOU SHOULD HAVE A  
17 SET OF SLIDES THAT WERE PASSED OUT. IF NOT, THEY  
18 ARE BEING SHOWN ON WEBEX.

19 SO WE HAVE AN APPLICATION THAT IS  
20 RESPONDING TO THE CLINICAL STAGE PROGRAMS. AS YOU  
21 KNOW, WE HAVE THREE OF THOSE. THIS IS TO THE CLIN2,  
22 CLINICAL TRIAL PROGRAM ANNOUNCEMENT.

23 A QUICK REMINDER OF THE SCORING SYSTEM  
24 THAT WE USE FOR THESE APPLICATIONS. APPLICATIONS  
25 UNDER THE CLINICAL PROGRAM ARE SCORED AS A 1, 2 OR A

1 3. A SCORE OF 1 MEANING THAT THE GRANTS WORKING  
2 GROUP PANEL CONSIDERED THIS AN APPLICATION WITH  
3 EXCEPTIONAL MERIT AND WARRANTS FUNDING. A SCORE OF  
4 2 NEEDS IMPROVEMENT AND DOESN'T WARRANT FUNDING, BUT  
5 IT HAS ELEMENTS THAT CAN BE ADDRESSED AND THEN BE  
6 RESUBMITTED. A SCORE OF 3 MEANS THAT IT IS  
7 SUFFICIENTLY FLAWED THAT IT DOESN'T WARRANT FUNDING.  
8 AND ALL APPLICATIONS ARE SCORED BY THE SCIENTIFIC  
9 MEMBERS OF THE GWG.

10 SO THIS APPLICATION, CLIN2-10411, IS A  
11 PROPOSAL FOR A PHASE 3 CLINICAL TRIAL OF A THERAPY  
12 THAT WILL ALLOW INDUCTION OF IMMUNE TOLERANCE IN  
13 PATIENTS WHO ARE RECEIVING A KIDNEY TRANSPLANT. THE  
14 THERAPY ITSELF IS A COMBINATION OF BLOOD STEM CELLS  
15 AND T-CELLS. AND THE GOAL OF THIS CLINICAL TRIAL IS  
16 TO COMPLETE PHASE 3, SUBMIT A BLA FOR APPROVAL BY  
17 THE FDA SO THAT IT CAN REACH PATIENTS.

18 AND THEN THE MAJOR PROPOSED ACTIVITIES  
19 UNDER THIS AWARD DURING THE PERIOD OR TENURE OF THE  
20 AWARD ARE TO MANUFACTURE THE CELL THERAPY PRODUCT,  
21 TO DEMONSTRATE THE PREDICTIVE VALUE OF ACHIEVING  
22 MIXED CHIMERISM, AND TESTING FOR CHIMERISM,  
23 DEMONSTRATE THE ABILITY TO ACHIEVE ULTIMATELY  
24 DURABLE IMMUNE TOLERANCE IN PATIENTS.

25 THE FUNDS REQUESTED ARE ABOUT \$18.7

1 MILLION. THERE IS A FULL FUNDING AMOUNT THAT IS  
2 BEING PROVIDED BY THE APPLICANT THAT IS EQUIVALENT  
3 TO THAT.

4 QUICK NOTE, THAT THIS APPLICATION CAME IN  
5 LAST YEAR. IT WAS SUBMITTED IN JULY, REVIEWED IN  
6 SEPTEMBER; AND SO, THEREFORE, THIS IS ONE THAT IS  
7 NOT YET ABIDING BY THE RULES THAT WERE PUT IN PLACE  
8 IN DECEMBER BY THE BOARD FOR THE CLINICAL PROGRAM.

9 THE GWG GAVE THIS A SCORE OF 1. THERE  
10 WERE 11 MEMBERS OF THE GWG THAT GAVE IT THAT SCORE.  
11 THERE WAS ONE MEMBER THAT GAVE IT A SCORE OF 2, NONE  
12 THAT GAVE IT A SCORE OF 3.

13 THE CIRM TEAM RECOMMENDATION IS TO FUND  
14 THIS APPLICATION; THAT IS, WE CONCUR WITH THE GWG  
15 RECOMMENDATION FOR AN AWARD AMOUNT OF \$18.7 MILLION.

16 MR. SHEEHY.

17 MS. BONNEVILLE: VERY QUICKLY I JUST WANT  
18 TO CONFIRM THAT OS STEWARD IS ON THE LINE.

19 DR. STEWARD: YES, I'M HERE.

20 MS. BONNEVILLE: THANK YOU, OS.

21 SUPERVISOR SHEEHY: SO DO I HAVE A MOTION  
22 TO ACCEPT THE CIRM TEAM'S RECOMMENDATION AND FUND  
23 THIS PROJECT?

24 DR. DULIEGE: I CAN MAKE THIS MOTION.

25 SUPERVISOR SHEEHY: DO I HAVE A SECOND?

1 DR. MARTIN: I'LL SECOND.

2 SUPERVISOR SHEEHY: THANK YOU. IS THERE  
3 ANY BOARD DISCUSSION? COMMENTS? QUESTIONS? OKAY.  
4 HEARING NONE, IS THERE ANY PUBLIC COMMENT?

5 DR. DEITCHER: HELLO. MY NAME IS STEVEN  
6 DEITCHER. I REPRESENT MEDEOR THERAPEUTICS. I WISH  
7 TO EXPRESS MY APPRECIATION FOR THE OPPORTUNITY TO  
8 BOTH SUBMIT THIS GRANT, DEFEND THIS GRANT, AND,  
9 HOPEFULLY, AT THE CONCLUSION OF THIS MEETING, BE  
10 FUNDED FOR THIS GRANT. AND WE'RE EXTREMELY EXCITED  
11 TO RECEIVE THE SUPPORT FOR THIS LATE STAGE CELLULAR  
12 PRODUCT DEVELOPMENT EFFORT.

13 IN PARTICULAR, I WOULD REALLY LIKE TO  
14 SHARE WITH THE BOARD MY COMMENDATION TO THE ENTIRE  
15 CIRM TEAM AND STAFF THAT WE INTERFACED WITH. IT'S  
16 VERY EASY TO BE CYNICAL AND NEGATIVE. I WILL ADMIT  
17 THAT MOST OF THE PARTIES THAT WE COME IN CONTACT  
18 WITH IN OUR BUSINESS ARE NOT VERY FUN TO DEAL WITH.  
19 I JUST WANT TO TELL YOU THAT THE PROFESSIONALISM,  
20 THE KNOWLEDGE BASE, AND THE COLLABORATIVE SPIRIT OF  
21 YOUR TEAM HERE EXCEEDED ANY EXPECTATIONS THAT I OR  
22 ANYONE ELSE COULD HAVE SET.

23 SO IT'S NICE TO SAY THAT THIS WAS AN  
24 ENJOYABLE PROSPECT AND PROJECT, AND WE LOOK FORWARD  
25 TO WORKING WITH THEM TO COMPLETE THIS TRIAL,

1 COMPLETE IT ON TIME, AND BRING THIS THERAPY TO  
2 PATIENTS, NOT ONLY IN CALIFORNIA, BUT THE REST OF  
3 THE UNITED STATES AND ACTUALLY GLOBALLY.

4 SO, AGAIN, I JUST WANT TO EXPRESS MY DEEP  
5 APPRECIATION.

6 SUPERVISOR SHEEHY: THANK YOU. ANY OTHER  
7 PUBLIC COMMENT?

8 SO, MARIA, WOULD YOU PLEASE CALL THE ROLL?

9 MS. BONNEVILLE: ANNEMARIE DULIEGE.

10 DR. DULIEGE: YES.

11 MS. BONNEVILLE: DAVID HIGGINS.

12 DR. HIGGINS: YES.

13 MS. BONNEVILLE: SHERRY LANSING.

14 MS. LANSING: YES.

15 MS. BONNEVILLE: DAVE MARTIN.

16 DR. MARTIN: AYE.

17 MS. BONNEVILLE: LAUREN MILLER.

18 MS. MILLER: YES.

19 MS. BONNEVILLE: ADRIANA PADILLA.

20 DR. PADILLA: YES.

21 MS. BONNEVILLE: JOE PANETTA.

22 MR. PANETTA: YES.

23 MS. BONNEVILLE: ROBERT QUINT.

24 DR. QUINT: YES.

25 MS. BONNEVILLE: JEFF SHEEHY.

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SUPERVISOR SHEEHY: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: DIANE WINOKUR.

MS. WINOKUR: YES.

MS. BONNEVILLE: MOTION CARRIES.

SUPERVISOR SHEEHY: I BELIEVE THAT  
CONCLUDES THE BUSINESS OF THE APPLICATION REVIEW  
SUBCOMMITTEE. BACK TO YOU, CHAIRMAN THOMAS.

CHAIRMAN THOMAS: THANK YOU, MR.  
SUPERVISOR.

DO WE HAVE ANY PUBLIC COMMENT ON ANY  
TOPICS AT ALL AT THIS POINT? HEARING NONE, THEN I  
BELIEVE THAT CONCLUDES TODAY'S MEETING.

THANK YOU, EVERYBODY. HOPE EVERYONE HAD A  
WONDERFUL HOLIDAY, AND WE'RE LOOKING FORWARD TO A  
GREAT YEAR BOTH AT CIRM AND FOR EVERYBODY  
PERSONALLY. AND WITH THAT, WE SHALL ADJOURN.

(THE MEETING WAS THEN CONCLUDED AT  
11:15 A.M.)

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE TELEPHONIC PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON JANUARY 18, 2018, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CA CSR 7152  
133 HENNA COURT  
SANDPOINT, IDAHO  
(208) 255-5453

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